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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,320	06/22/2001	Clifton E. Barry III	015280-413100US	7214

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EXAMINER	
SAKELARIS, SALLY A	
ART UNIT	**PAPER NUMBER**
1634	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/888,320	Applicant(s) BARRY ET AL.	
	Examiner Sally A Sakelaris	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-12, 16, 21, 22-24, drawn to methods of detecting a mutation in the nucleic acids of the EtaA gene classified in Class 536, subclass 6.

II. Claims 1-4, 13-15, 16, and 21 drawn to methods of detecting a mutation in a protein by the specific binding of an antibody classified in Class 435, subclass 7.1.

III. Claims 1-4, 16, 17-20, and 21 drawn to a method of detecting a mutation by determining the ability of Mycobacterium to oxidize a thioamide or a thiocarbonyl through an oxidation assay classified in Class 435 subclass 4.

IV. Claims 25-29 drawn to a kit to determine the ability of Mycobacterium to oxidize a thioamide or a thiocarbonyl through the use of nucleic acids, Class 514, subclass 8.

V. Claim 30 drawn to a kit that determines the ability of Mycobacterium to oxidize a thioamide or a thiocarbonyl through the use (2-ethyl-pyridin-4-yl)methanol, Class 530, subclass 388.9 and 389.8

VI. Claim 31 drawn to a kit that determines the ability of Mycobacterium to oxidize a thioamide or a thiocarbonyl through the use a radiolabeled ethioamide, Class 514, subclass 8.

VII. Claim 32 drawn to a kit that determines the ability of Mycobacterium to oxidize a thioamide or a thiocarbonyl through the use of an antibody that specifically binds to a product of the EtaA gene, Class 530, subclasses 388.4 and 389.5.

VIII. Claim 33 drawn to a kit that determines the ability of Mycobacterium to oxidize a thioamide or a thiocarbonyl through the use of an antibody that specifically binds to (2-ethyl-pyridin-4-yl)methanol, Class 514, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

The methods of inventions I, II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially distinct methods, which require the use of different reagents, have different process steps and have distinct objectives. The method of invention I requires the use of DNA and involves performing nucleic acid amplification steps, hybridization assays and/or sequencing analysis in order to accomplish the objective of determining the presence of a mutation in a nucleic acid sequence which confers a resistance of a bacterium to a thioamide or thiocarbonyl drug or pro-drug. The method of invention II requires the use of protein and involves performing ligand binding assays, isoelectric focusing and/or gel electrophoresis mobility assays in order to accomplish the objective of detecting the presence of a mutant protein which confers a resistance of a bacterium to a thioamide or thiocarbonyl drug or pro-drug. (detecting mutation with antibody though?) Finally, the method of invention III requires the use of an assay to detect the oxidative state of a thioamide or thiocarbonyl. The detection of said oxidative state will serve to detect the presence of a mutant protein. In the instant case the different inventions of detecting mutations in nucleic acids, proteins, and via an assay for oxidative states, all have different functions and are not disclosed as capable of use together.

The methods of invention I are unrelated to the kit inventions V, VI, VII, and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the methods for detecting mutations in nucleic acids do not require the components of the kit inventions IV-VIII.

The methods of invention II are unrelated to the kit inventions IV, V, VI, and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the methods for detecting mutations in proteins do not require the components of the kit inventions IV-VI & VIII.

The methods of invention III are unrelated to the kit inventions IV and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the methods for detecting mutations through an oxidative assay do not require the components of the kit inventions IV & VII.

Inventions IV, V, VI, VII, and VIII are unrelated to each other if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case,

the different inventions are not disclosed as capable of use together and the kits each contain unique chemical reagents that are structurally and functionally distinct.

The inventions of groups I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The nucleic acids of the kits invention IV can be used in a materially different process such as for the synthesis of peptides or for general methods to detect mycobacteria.

The inventions of groups II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of the kits in invention VII can be used for a materially different process such as for isolating proteins.

The inventions of groups III and V, III and VI, and III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the components of the kits of inventions V, VI, and VIII can be used in a materially different process such as for

determination of ligand stearic properties, halogen additions, and in the study of transition metal-carbon single bonding.

2. If Applicant elects inventions I-IV or VII, further restriction is required as each of these following mutations are distinct:

Group 1- deletion at position 63

Group 2- addition at position 567

Group 3- addition at position 811

Group 4- amino acid substitution G43C

Group 5- amino acid substitution P51L

Group 6- amino acid substitution D58A

Group 7- amino acid substitution Y84D

Group 8- amino acid substitution T186K

Group 9- amino acid substitution T342K

Group 10- amino acid substitution A381P

Each of these mutations are considered to be structurally and functionally distinct from each other and absent evidence to the contrary, each mutation is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14.

3. Further, if Applicant elects inventions I or IV applicant must also elect a single pair of primers corresponding to the EtaA gene from SEQ ID NO's 3-14. Each primer pair is considered to be structurally distinct from the other primer pairs because each sequence is structurally and functionally distinct. Further, a search of, for example, primers consisting of

SEQ ID NO:3 and 4 would not be co-extensive with a search of primers consisting of SEQ ID NO: 5 and 6. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14.

Because these invention are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VIII require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantai Dessau whose telephone number is (703)605-1237.

CARLA J. MYERS
PRIMARY EXAMINER